

### **REMARKS**

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

#### **I. DISPOSITION OF THE CLAIMS**

Claim 2 is requested to be cancelled. Claims 1 and 5-6 are currently being amended. Claims 18-19 are being added.

No new matter has been added. Claim 1 had been amended to incorporate the limitations of claim 2. Claims 18-19 are drawn to subject matter canceled from claims 5-6.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 1-19 are now pending in this application. Claims 10-17 are withdrawn as non-elected. Claims 1, 3-9, and 18-19 are under examination.

#### **II. INDEFINITENESS**

Claims 5-6 stand rejected as indefinite for reciting “preferably”. Office Action, page 3, last 2 paragraphs.

Applicants have obviated this ground of rejection by deleting the clauses reciting preferable embodiments. Accordingly, this ground of rejection should be withdrawn

#### **III. OBVIOUSNESS**

The claims stand rejected as obvious over US 6,027,747 (Terracol) and US 4,016,254 (Seager).

The Office applied Terracol for its disclosure of forming a co-precipitate of an active agent around a hydrophilic carrier by spraying an organic solution containing the active agent.

The Office acknowledges that Terracol does not disclose milling the formulation nor the repetition of milling and spraying. Office Action, page 5, lines 11-12.

The Office applies Seager for its disclosure of milling a pharmaceutical formulation. The Office does not assert that Seager discloses multiple milling and spraying steps. Nevertheless, the Office concludes that it would have been obvious to bridge this gap, because a person of ordinary skill in the art would expect that repeating the milling and spraying steps would be advantageous. Office Action, page 5, line 13, to page 6, line 2.

Alternatively, the Office asserts that “adding spraying and milling steps one or more times, which are well-known process in the pharmaceutical art, would be obvious”. Office Action, page 6, lines 4-5.

Applicants traverse, because Terracol and Seager do not fairly suggest the invention and its advantages.

“All words in a claim must be considered in judging the patentability of that claim against the prior art.” M.P.E.P. § 2143.03, quoting *In re Wilson*, 424 F.2d 1382, 1385 (C.C.P.A. 1970). “[T]here must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, 82 U.S.P.Q.2d 1385, 1391 (2007). Here, the Office has not met its burden to provide the required “articulated reasoning with some rational underpinning” .

Here, the Office’s reasoning lacks rational underpinning, because the rejection failed to consider fully the meaning of the limitations expressed as the following sequence of steps of claim 1 as amended (emphasis added):

- b) spraying a portion of the solution obtained in a) over the neutral hydrophilic carriers,
- c) milling the particles obtained in stage b),
- d) spraying the remaining amount of the organic solution over the particles milled in stage c)
- e) final milling of the particles obtained in stage d).

The Office apparently considered claim 1 as reciting the equivalent of multiple spraying steps and multiple milling steps, where the repetition of a beneficial step could be

considered an obvious variation. Instead, claim 1 recites repeated cycles of the two steps of spraying and milling, where the solution from a) is sprayed in two portions. The cited references give no indication that such steps could be beneficial.

To the contrary, the art of record discloses disadvantages of milling. Seager discloses that milling presents drawbacks in yielding “disadvantageous dust” (column 1, line 63, to column 2, line 4). In view of this disclosure, a person of ordinary skill in the art would not be led to carry out multiple milling steps yielding the drawback of dust formation with no expectation of any benefits.

Moreover, Applicants have found that the claimed invention yields less agglomeration and an improved dissolution profile. See paragraph page 1, [0018], page 5, paragraph [0125], and Figure 2. Evidence pertaining to secondary considerations must be taken into account whenever present. M.P.E.P. § 2145, citing *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1372 (Fed. Cir. 2007).

Taken as a whole, claim 1 would not have been obvious over Terracol and Seager.

Claims 1, 3-9, and 18-19 depend directly or indirectly from claim 1 and thus are also non-obvious. If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. M.P.E.P. § 2143.03, quoting *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Accordingly, Applicants request that this ground of rejection be withdrawn for all claims under examination.

#### **IV. OBVIOUSNESS-TYPE DOUBLE PATENTING (ODP)**

The claims stand provisionally rejected for ODP over co-pending application 10/564,845 (published as US 2006/0172010).

The Manual of Patent Examining Procedure instructs examiners as follows regarding ODP (M.P.E.P. § 804.I.B.1):

If a “provisional” nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer.

Here, the present application is the earlier-filed application. The present application has an earlier effective filing date (PCT filed July 16, 2004) than application 10/564,845 (PCT filed July 19, 2004). Thus, the present application should be allowed to issue without terminal disclaimer if the claims are deemed allowable.

Applicants request that the Office hold this ground of rejection in abeyance pending indication of allowable subject matter. Upon such indication of allowable subject matter in the present application, Applicants request withdrawal of the ODP rejection for the present application.

### **CONCLUSION**

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By 

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